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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/403,429 10/20/99 SHIMIZU

T 2535USOP

023115 HM12/1027  
TAKEDA PHARMACEUTICALS AMERICA, INC  
INTELLECTUAL PROPERTY DEPARTMENT  
475 HALF DAY ROAD  
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LINCOLNSHIRE IL 60069

EXAMINER

TRAN.S

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/27/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/403,429**

Applicant(s)  
**Shimizu et al.**

Examiner  
**Susan Tran**

Group Art Unit  
**1615**



☒ Responsive to communication(s) filed on Sep 13, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-19 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

Receipt is acknowledged of applicants' Preliminary Amendment A filed 10/20/99, Request to Withdraw Attorney filed 06/28/00, and Amendment B filed 09/13/00.

#### ***Response to Arguments***

1. Applicant's arguments filed 09/13/00 have been fully considered but they are not persuasive. The examiner maintains the original rejections, and thus claims 1-7, 9, and 13-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ohno et al. USPN 5,958,453 ('453), and claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al. ('453), in view of Shashoua et al. USPN 5,795,909.

Applicants argue that Ohno does not teach a low-substituted hydroxypropyl cellulose having 5% by weight or more to less than 7% by weight of hydroxypropyl group for a rapidly disintegrable solid solution. However, the examiner relies on the teaching of Ohno in column 6, lines 59-62 wherein the solid pharmaceutical having fast disintegrability and dissolubility in the oral cavity. Thus, it is the position of the examiner that fast disintegrability and dissolubility and applicants invention is substantially equivalent absent the presentation of some unusual and/or unexpected result that accrues from the claimed limit. Furthermore, the burden is placed upon the applicants to establish that the reference's low-substituted hydroxypropyl cellulose does not have the claimed weight percent of hydroxypropyl group. Applicants attention is further directed

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to column 5, lines 42-53, wherein mannitol can be further added to the composition and the composition is dissolve or disintegrate without being swallowed.

Applicants argue that Shashoua does not mention any solid formulations nor claimed range of hydroxypropyl group. However, the examiner relies on the teaching of Shashoua mainly for the teaching of active ingredients, and further the examiner refers to the teaching of Shashoua in column 48, lines 18 through column 49, lines 1-45, wherein the pharmaceutical composition also comprising pharmaceutical acceptable carrier in solid form for oral administration such as capsules, cachets, tablets or lozenges.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER / 600